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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,190	02/28/2002	Pia M. Challita-Eid	511582003420	7796

36327 7590 12/28/2006

AGENSYS C/O MORRISON & FOERSTER LLP
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EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/087,190	CHALLITA-EID ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *83-110* is/are pending in the application.

4a) Of the above claim(s) *86-110* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Exhibit A*.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 June 2006 has been entered.

2. Claims 1-82 are cancelled.
Claims 83-110 are pending.

3. Applicant's election of the invention recited in claims 83-87 and the species of SEQ ID NO:5 in the reply filed on 10/10/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 86-110 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

5. Claims 83-85 are under consideration to the extent that the transcript variant encodes the protein of SEQ ID NO:5, i.e., applicants' elected species.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. This office Action contains New Grounds of Rejections

Objections/Rejections Withdrawn

8. *All objections/rejections set forth in the office action mailed 2/17/06 are withdrawn in view of the cancellation of the claims.*

New grounds of Objections/Rejections

Specification

9. The disclosure is objected to because of the following informalities:
a. Applicants' benefit claim to USSN 09/779,250 on the first line of the specification should be updated tom indicate this application is now U.S. Patent No. 6,924,358.

b. The specification (substitute filed 11/10/03) at pg. 63, lines 7-8 needs to be updated with the complete address for the ATCC, i.e., 10801 University Boulevard, Manassas, VA 20110-2209.

c. The use of the trademark Epimatrix ™ and Epimer ™ has been noted in this application on page 24, line 25 (substitute spec, filed 11/10/03). Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Applicants' cooperation is requested in reviewing the entire disclosure for additional trademarks that require correction (e.g., pg. 42, lines 28 and 30).

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Appropriate correction is required.

10. The substitute specification filed 10 November 2003 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: an accompanying clean version (without markings) and a statement that the substitute specification contains no new matter were not supplied.

A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) as discussed supra.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown. Applicant is reminded to incorporate all previous amendments and those required in the instant Office Action to the specification to avoid confusion and mistake during the issue and printing processes of the present application.

Drawings

11. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the replacement drawings filed 1/28/03 are not of sufficient quality and will result in a delay during the issue and printing processes of the present

application. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

Replacement Drawing Sheets

Drawing changes must be made by presenting replacement sheets which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments section, or remarks, section of the amendment paper. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). A replacement sheet must include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and within the top margin.

Annotated Drawing Sheets

A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be submitted or required by the examiner. The annotated drawing sheet(s) must be clearly labeled as "Annotated Sheet" and must be presented in the amendment or remarks section that explains the change(s) to the drawings.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

12. Claims 83-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the recitation "121P1F1 gene (SEQ ID NO:1)" in claim 83. According to Genes IV (Lewin B., Oxford University Press, page 810, 1990), a gene is defined as "the segment of DNA involved in producing a polypeptide chain; it includes regions preceding and following the coding regions (leader and trailer) as well as intervening sequences (introns) between individual coding segments (exons)." From the teachings of the specification, however, the nucleic acid sequences introducing antigens or marker elements appear limited to the specific coding regions, and do not include expression control elements that fall under the definition of a gene. Accordingly, the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants' attention is directed to Figs. 1 and 2 in which Fig. 1 discloses SEQ ID NO:1, which is presumably the 121P1F1 gene, however, Fig. 2 discloses a sequence that appears to be longer and is the coding sequence for the polypeptide of SEQ ID NO:2. Given the additional structural elements of a "gene" relative to the coding sequence, one of skill in the art would not be reasonably apprised of the metes and bounds of the claims where the "gene" of SEQ ID NO:1 is apparently shorter than the coding sequence. Further, is the sequence shown in Fig. 1 the same as the coding sequence shown in Fig. 2?

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

14. Claims 83-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated 121P1F1 transcript or transcripts that encode the protein of SEQ ID NO:2, does not reasonably provide enablement for: (i) any isolated 121P1F1 transcript variant that encodes a protein comprising at least one amino acid substitution, addition or deletion relative to SEQ ID NO:2 or the transcript variant of SEQ ID NO:5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The claims as written encompass a large genus of transcript variants of 121P1F1 (SEQ ID NO:1) and encoded peptide and polypeptide amino acid sequences. The genus encompasses peptides wherein such peptides have numerous differences in amino acid sequence and function.

Applicant discloses an isolated 121P1F1 protein of SEQ ID NO:2 that is encoded by a nucleotide sequence of SEQ ID NO:1 that is highly expressed in prostate cancer and a method of producing said protein in the instant specification (see overlapping pages 13-14, 17 and Example 7 in particular). Applicant has not taught how to make and/or use (i) any isolated 121P1F1-related protein or any fragment of said protein, or (ii) the structural and functional characteristics of any isolated 121P1F1-related protein or any fragment of said protein, or (iii) any isolated 121P1F1-related protein that has an amino acid sequence encoded by a polynucleotide that comprises at least one amino acid substitution, addition or deletion, broadly embracing disparate protein sequences and proteins that differ functionally.

Applicant has not provided sufficient biochemical information (e.g. structural characteristics, amino acid composition, physicochemical properties, etc) that distinctly identifies (i) any isolated 121P1F1-related protein or any fragment of said protein, or (ii) the structural and functional characteristics of any isolated 121P1F1-related protein or any fragment of said protein, or (iii) any isolated 121P1F1-related protein that has an amino acid sequence encoded by a polynucleotide that comprises at least one amino acid substitution, addition or deletion. The specification does not appear to have provided sufficient guidance as to which isolated 121P1F1-related protein or any fragment of said protein would share the same function as the 121P1F1 protein of SEQ ID NO:2. Neither does the specification appear to have provided any working examples of any 121P1F1-related protein or fragments of said protein that have the same functional activities or characteristics, i.e., highly expressed in prostate cancer as 121P1F1 protein.

Further, the specification discloses 121P1F1-related proteins as proteins that share 70% ,75%, 80% ,85% ect. similarity with the 121P1F1 protein having the amino acid sequence of SEQ ID NO:2 and polynucleotides encoding a 121P1F1-related protein and fragments thereof and encoding about amino acid 1 to about amino acid 10 of the 121P1F1 protein (see pp. 13-17 and 20-22, in particular). Attwood (Science 2000; 290:471-473) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences. Similarly, Skolnick et al. (Trends in Biotech. 2000; 18(1):34-39) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess

as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Finally, even single amino acid differences can result in drastically altered functions between two proteins. For example, Metzler et al. (Nature Structural Biol. 1997; 4:527-531) show that any of a variety of single amino acid changes can alter or abolish the ability of CTLA4 to interact with its ligands CD80 and CD86 (e.g., summarized in Table 2). Thus it is unpredictable if any functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences.

In view of this unpredictability; the skilled artisan would not reasonably expect a polypeptide having anything less than 100% identity *over the full length of SEQ ID NO:2* to *share the same function* as the 121P1F1 protein having the amino acid sequence of SEQ ID NO:2. The limitation "which induces a specific antibody response" is not seen as providing a requisite functional activity since an antibody epitope may be as small as 6-15 shared amino acid residues (e.g., Lerner Nature 1982; 299:592-596, see page 595-596) and places no limitations on the function of the protein containing the polypeptide sequence recognized. Thus the recitation of percent identity language, in the absence of *a testable function* and limitations regarding the *sequence length over which the percent identity is required (i.e., SEQ ID NO:5)*; does not allow the skilled artisan to make and use (i) any isolated 121P1F1-related protein or any fragment of said protein, or (ii) the structural and functional characteristics of any isolated 121P1F1-related protein or any fragment of said protein, or (iii) any isolated 121P1F1-related protein that has an amino acid sequence encoded by a polynucleotide that comprises at least one amino acid substitution, addition or deletion commensurate in scope with the instant claims without undue experimentation.

Protein chemistry is probably one of the most unpredictable areas of biotechnology . It is known in the art that even single amino acid changes or differences in a proteins amino acid sequence can have dramatic effects on the protein's function. For example, Mikayama et al. (PNAS, 1993. 90: 10056-10060) teach that the human glycosylation factor (GIF) protein differs from human macrophage migration inhibitory factor (MIF) by a single amino acid residue (see Figure 1 in particular). Yet, Mikayama et al. further teach that GIF is unable to carry out the function of MIF and MIF does not demonstrate GIF activity (see Abstract in particular). Burgess et al (J Cell Biol. 111:2129-2138, 1990) show that a conservative replacement of a single "lysine" reside at position 118 of acidic fibroblast growth factor by "glutamic acid" led to the substantial loss of heparin binding, receptor binding and biological activity of the protein. Similarly, Lazar et al. (Mol Cell Biol. 8:1247-1252, 1988) teach that in transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagines did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen. These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein. Furthermore, the specification fails to teach what deletions, truncations, substitutions and mutations of the disclosed sequence can be tolerated that will allow the protein to

function as the protein of SEQ ID NO:2, if known. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with reasonable expectation of success are limited. Certain positions in the sequence are critical to the three-dimensional structure/function relationship, and these regions can tolerate only conservative substitutions or no substitutions.

Since the amino acid sequence of a polypeptide determined its structural and functional properties, predictability of which fragments will retain functionality requires knowledge of, and guidance with regard to, which amino acids in the polypeptide's sequence contribute to its structure, and therefore, function. The problem of predicting which fragments or derivatives of a protein will retain functionality and which will not is complex and well outside the realm of routine experimentation. Because of the lack of sufficient guidance and predictability in determining which structures would lead to functional proteins or peptides with the desired properties and that the relationship between the sequence of a peptide and it's tertiary structure (i.e. its activity) was not well understood and was not predictable (e.g. see Ngo et al, in The Protein Folding Problem and Tertiary Structure Prediction, 1994. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.); it would require an undue amount of experimentation for one of skill in the art to arrive at the breadth of proteins encompassed by the claimed invention. Without sufficient guidance, the changes which can be made in the structure of 121P1F1 protein and still maintained its biological functions is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use (i) any isolated 121P1F1-related protein or any fragment of said protein, or (ii) the structural and functional characteristics of any isolated 121P1F1-related protein or any fragment of said protein, or (iii) any isolated 121P1F1-related protein that has an amino acid sequence encoded by a polynucleotide that comprises at least one amino acid substitution, addition or deletion in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the absence of working examples, and

the limited amount of direction provided given the breadth of the claims, it would take undue experimentation to practice the claimed invention.

15. Claims 83-84 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of a transcript or nucleic acid encoding the isolated 121P1F1 protein of SEQ ID NO:2.

Applicant is not in possession of: (i) the genus of isolated 121P1F1-transcript variants that encode a protein comprising at least one amino acid substitution, addition or deletion relative to SEQ ID NO:2 and (ii) a 121P1F1 gene.

Applicant has disclosed the transcript of SEQ ID NO:1, which encodes the protein of SEQ ID NO:2 and a limited number transcript variant species. The specification does not describe any of the structural elements of a 121P1F1 gene that would encode these cDNA sequences. For example, the specification does not describe the organization, location or actual DNA sequences of promoter and regulatory regions and introns, all defining elements of a "gene". The art indicates that the structure of genes with naturally occurring regulatory elements and untranslated regions is empirically determined. For example, the structural elements of a "gene" mediating the expression of a particular protein in the liver may be different than the structural elements of the "gene" mediating the expression of the same protein in the brain. Therefore, the structure of these elements which applicant considers essential to the function of the claims are not conventional in the art. The specification lacks information to lead one of skill in the art to understand that the applicant had possession of the broadly claimed invention at the time the instant application was filed. Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed. Conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The sequences themselves are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

A description of what a material does (i.e. induces a specific antibody) rather than of what it is, usually does not suffice. The patent does not more than describe the desired function of the compound called for and contains no information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention. At best, it simply indicates that one should run tests on a wide spectrum of

compounds in the hope that at least one of them will work. Inadequate written description that merely identifies a plan to accomplish an intended result "is an attempt to preempt the future before it has arrived". *Fiers v. Revel*, 984 F.2d 1164,11719 Fed.Cir. 1993).

For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. Cf. In re Bell, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993), and In re Deuel, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995) (holding that a process could not render the product of that process obvious under 35 U.S.C. 103). The Federal Circuit has pointed out that under United States law, a description that does not render a claimed invention obvious cannot sufficiently describe the invention for the purposes of the written description requirement of 35 U.S.C. 112. Eli Lilly, 119 F.3d at 1567, 43 USPQ2d at 1405. While applicant has provided limited species (i.e., transcript encoding SEQ ID NO:5) that fall within the claimed genus, the written description does not convey a representative number of species that fall within the claimed genus because the genus is highly variant and it is not obvious from the disclosure of the limited species, what other species will function equivalently.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Therefore, only transcripts that encode the protein of SEQ ID NO:2 polypeptide, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

16. Claims 83-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al (US Patent 6,569,662, filed 7/19/2000).

US Patent '662 discloses an isolated novel protein, and fragments thereof, wherein the protein or fragment thereof is encoded by a nucleotide sequence of SEQ ID:1092, which

is 100 % identical to the nucleotide sequence fragment of claimed SEQ ID NO:1 (see Exhibit A attached) and thus, is interpreted as a transcript variant of SEQ ID NO:1 encoding a protein that comprises at least one amino acid deletion relative to SEQ ID NO:2.

Thus, Tang et al anticipates the claimed invention.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

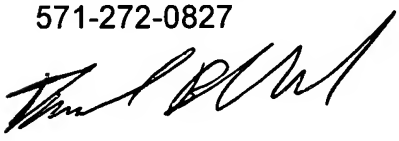

Exhibit A

RESULT 4
US-09-620-312D-1092/c
; Sequence 1092, Application US/09620312D
; Patent No. 6569662
; GENERAL INFORMATION:
; APPLICANT: Tang, Y. Tom
; APPLICANT: Liu, Chenghua
; APPLICANT: Asundi, Vinod
; APPLICANT: Zhang, Jie
; APPLICANT: Ren, Feiyan
; APPLICANT: Chen, Rui-hong
; APPLICANT: Zhao, Qing A.
; APPLICANT: Wehrman, Tom
; APPLICANT: Xue, Aidong J.
; APPLICANT: Yang, Yonghong
; APPLICANT: Wang, Jian-Rui
; APPLICANT: Zhou, Ping
; APPLICANT: Ma, Yunqing
; APPLICANT: Wang, Dunrui
; APPLICANT: Wang, Zhiwei
; APPLICANT: John Tillinghast
; APPLICANT: Drmanac, Radoje T.
; TITLE OF INVENTION: No. 6569662el Nucleic Acids and
; TITLE OF INVENTION: Polypeptides
; FILE REFERENCE: 784CIP2B
; CURRENT APPLICATION NUMBER: US/09/620,312D
; CURRENT FILING DATE: 2000-07-19
; PRIOR APPLICATION NUMBER: 09/552,317
; PRIOR FILING DATE: 2000-04-25
; PRIOR APPLICATION NUMBER: 09/488,725
; PRIOR FILING DATE: 2000-01-21
; NUMBER OF SEQ ID NOS: 1105
; SOFTWARE: pt_FL_genes Version 1.0
; SEQ ID NO 1092
; LENGTH: 1243
; TYPE: DNA
; ORGANISM: Homo sapiens
; FEATURE:
; NAME/KEY: CDS
; LOCATION: (319)..(891)
US-09-620-312D-1092

Query Match 100.0%; Score 254; DB 3; Length 1243;
Best Local Similarity 100.0%; Pred. No. 7.8e-71;
Matches 254; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy          1 GATCACAGTCTTTGTATTTTTCTACTTCTGCCTTTAGCTGTTCCCTTTGGTCTCGAAGTG 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        718 GATCACAGTCTTTGTATTTTTCTACTTCTGCCTTTAGCTGTTCCCTTTGGTCTCGAAGTG 659

Qy         61 AAGAAAGCTCTTTTGCTAGCCTGGTTCGCTCTTCCGTTTCACATCGGCCAATTTTAGCTT 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        658 AAGAAAGCTCTTTTGCTAGCCTGGTTCGCTCTTCCGTTTCACATCGGCCAATTTTAGCTT 599

Qy        121 TCTCAATGCTTTTCTGTAGGCTTGCATGCTTTTGACTTCCCTCAGACAACTGAGATTCCA 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        598 TCTCAATGCTTTTCTGTAGGCTTGCATGCTTTTGACTTCCCTCAGACAACTGAGATTCCA 539
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Qy        181 GAACCTCCAACTTATGTTTCCTTGCATGAAGAGCTTTACTTGGAAAAGCCCAATAATAAT 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        538 GAACCTCCAACTTATGTTTCCTTGCATGAAGAGCTTTACTTGGAAAAGCCCAATAATAAT 479

Qy        241 TAGAAGTTCCGATC 254
              ||||||||||||||
Db        478 TAGAAGTTCCGATC 465
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